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FIG. 1

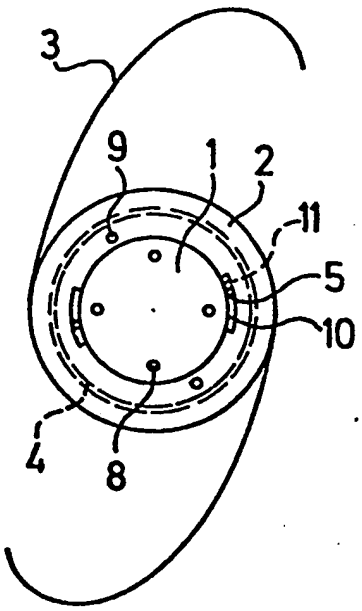


FIG. 2

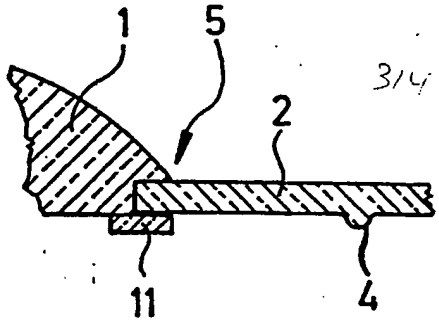
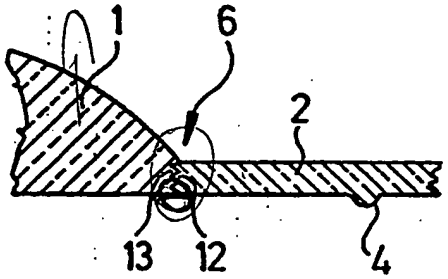


FIG. 4



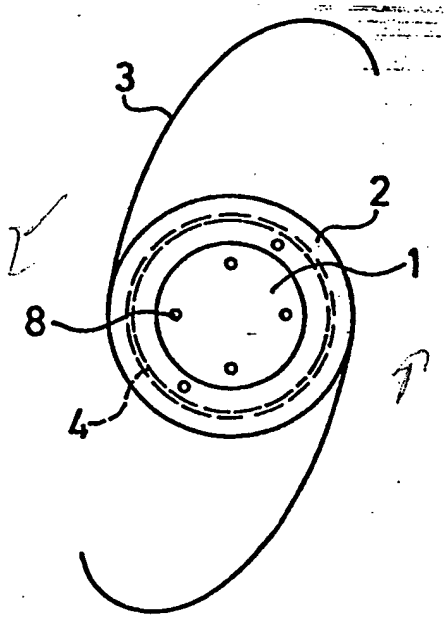
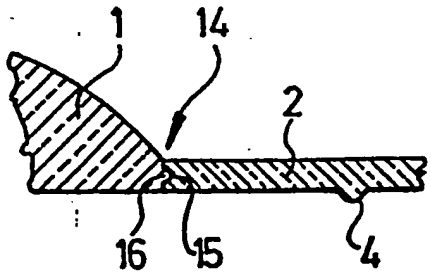


FIG. 3

FIG. 5



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INTRAOCULAR LENS
[Intraocularlinse]

Rainer Rochels

UNITED STATES PATENT AND TRADEMARK OFFICE
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Description

/1*

The invention concerns an intraocular lens in accordance with the preamble of Patent Claim 1, as described in not previously published DE 35 03 690 C1. The intraocular lens shown there can be implanted in the capsular bag and consists of a frame together with haptics and a lens that can be inserted separately into the frame, whereby the fitting together of the frame and lens occurs before implantation of the intraocular lens and exchange of the lens in the frame is not provided for when it is present in the eye.

Intraocular artifical lenses (intraocular lenses), thus, for example, the previous, are used world wide as therapy especially in older patient with cataracts. The outcome of lens implantation in adulthood can be considered excellent.

Examples of a number of possible forms of intraocular lens are also known from DE-OS 33 03 803. The intraocular lenses available for implantation at that time can be characteristically placed in four classes according to their fastening location in the eye, namely anterior chamber lenses (for example, known from US-PS 40 41 552) iris supported lenses (for example, known from US-PS 43 04 012), posterior chamber lenses (for example, known from US-PS 41 59 546) and endocapsular lenses (for example, known from US-PS 43 65 360).

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*Numbers in the margin indicate column in the foreign text.

Artificial lens implantation available today for treatment of cataracts in adulthood occurs with posterior chamber lenses, whereby after removal of lens opacity, with stress on the clear, posterior lens capsule, through the pupil of the iris, the lens in most cases is fastened to bow-shaped haptics in a cut in the vitreous humor of the eye.

However, lens opacity occurs not only in old age, but already in childhood. The present invention is concerned with therapy for lens opacity in childhood.

Lens opacity in childhood results either already during pregnancy through metabolic disturbances, genetic disturbance or in the context of combined malformation of the eye or the entire body. A very frequent mode of occurrence is drastic eye injury in early childhood with subsequent lens opacity. The form and extent of lens opacity can be extremely varied according to the cause. In practically all cases such lens opacity leads to incident light in the eye no longer being able to be sharply projected on the retina. This causes in older children a clear decrease in ability to see that can not be improved even by correction with glasses or contact lenses. Much more grave is lens opacity in early childhood. The new born can only perceive light and dark due to the immaturity of the entire visual apparatus (eyes and brain). Vision must be first learned exactly like other body functions. According to the most recent investigations, one must assume this very narrowly limited phase runs from the first four to six months in humans. If in this

time vision is not learned for any reason, the eye is later not in a position to achieve complete visual sharpness. This is also not possible through the wearing of glasses. Weak vision results.

From this it follows that children with congenital lens opacity do not learn to see at all and even later, for example, after operative removal of lens opacity are no longer in a position to achieve complete visual sharpness. /2

With injuries to the eye in childhood that lead to lens opacity, the situation is somewhat more favorable when the child at approximately the age of three to four years old already has stable development of eyesight. From many clinical observations one knows that even at this age, for example, after a drastic eye injury with lens opacity, eyesight can be terminally lost again. Even in this case an improvement in visual sharpness can no longer be achieved through glasses or contact lenses.

In accordance with the present state of knowledge, one assumes that a congenital lens opacity should be removed as early as possible after birth and a injury-caused lens opacity in childhood should likewise be operatively removed as quickly as possible after the injury. The known operation techniques and instruments allow removal without complications of practically all cases of congenital or acquired lens opacity in childhood. In this manner clearly refracting medians are thus obtained in the eye that allow incident light to fall on the retina, however the result thus obtained also has serious consequences. A

child's eye is through removal of the lens opacity displaced to another state of refractive power that no longer allows focused refraction onto the retina. A human lens represents a strongly refracting magnifying glass that with exception of in old age is in a position because of the near adjustment reaction (accommodation) to refract images from various distances sharply onto the retina. If the lens fails, accommodation is no longer present. Further, beams of light coming parallel from a distance into the eye can no longer be focused as a point on the retina. Hereby, an unusable visual sharpness results. At least newborns and very young children, due to these consequences, never learn to see and remain visually weak. This weak vision is a very serious complication of loss of lenses that makes the eye functionally unusable. Further complications of lens loss and weak vision caused by this are subsequent squinting of the eyes and the inability to learn spatial vision.

To remedy congenital or acquired lens opacity in children a series of therapeutic possibilities through glasses, contact lenses or intraocular artificial lenses has been investigated in detail and the results summarized in publications. Hereby, the following list of literature is referenced:

Apple, D.J., Mamlis, N., Loftfield, K., Googe, J.M., Novak, L.C., Kavkavan Norman, D., Brady, S.E., Olson, R.J.: Complication of intraocular lens. A historical and histophatological review. Surv. Ophthalmol. 29:1-54, 1984.

Apple, D.J., Mamlis, N., Reidy, J.J., Novak, L.C., Googe, J.M., Loftfield, K., Olson, R.J.: Comparison of ciliary and capsular bag fixation of posterior chamber intraocular lens. Am. Intra-Ocular Implant Soc. J. 11:44-63, 1985.

Hiles, D.A.: Visual acuities of monocular IOL and non-IOL aphakic children. Ophthalmology 87:1296-1300, 1980 b. /3

Hiles, D.A. (ed.): Intraocular lens implants in children. Grune & Stratton, 1980a.

Hiles, D.A.: Intraocular lens implants in children with monocular cataracts. Ophthalmology 91:1231-1237, 1984.

Fyodorov, S.N.: The results of intraocular lens correction of aphakia in children. In: Hiles, D.A. (ed.), Intraocular lens implants in children. pp. 179-188. Grune & Stratton, 1980.

Ben Ezra, D., Paez, J.H.: Congenital cataract and intraocular lenses. Amer. J. Ophthal. 96:311-314, 1983.

Gordon, R.A., Donzis, P.B.: Refractive development of the human eye. Arch. Ophthalmol. 103:785-789, 1985.

A comparison of the results obtained with various treatments clearly speaks for optical correction by an intraocular lens even in children with congenital or acquired lens opacity. A characteristic point of view has remained unconsidered in the previously carried out investigations. The eye length of an adult is ca. 24 mm. This change in length allows considerable change in the necessary refractive power of the lens to be implanted to achieve a sharp retina image. This means that a child's eye, in comparison to an adult's eye, is very strongly

far sighted. This leads to a problem not yet discussed in the subject literature of a suitable choice of refractive power for the lens to be implanted.

If in a newborn an artificial lens is implanted whose refractive power is adjusted to the length of the eyeball, a lens must be chosen with a +35 dptr refractive power. In the first year of life due to the growth in length of the child's eye an already much weaker lens (approximately +28 dptr.) is required, in the second year of life, a lens of approximately +24 dptr and in the sixth year of life, a lens of +20 dptr. Since a child's, as also an adult's eye, can accept at most a change in refractive power of 3 dptr, without inducing an unsharp retina image, which would inevitably lead to weak vision, treatment of congenital and acquired lens opacity through artificial lens implantation requires numerous operative exchanges of the artificial lens to prevent weak vision.

Anterior chamber lenses and iris supported lenses already mentioned in the introduction are hereby ruled out, since tissue grows into them at their fixation location and an exchange of these lenses would lead to considerable tissue traumatization. The same is also true for artificial lenses that are fixed in the posterior chamber of the eye in the vitreous humor. In the later, in addition to growth in the length of the eye, a growth in the width also occurs, which can lead to slipping of the lens. With endocapsularly implanted artificial lenses, the entire capsular bag must be taken out of the eye when exchanged.

Thereby, it is no longer possible to endocapsularly implant a new artificial lens fitted to the refractive power of the eye.

The goal of the invention is therefore to provide an intraocular lens of the type mentioned in the introduction that insures treatment of congenital or acquired lens opacity through implantation of an artificial lens, without, thereby, the danger of weak vision being present due to change in the refractive power due to growth in the length of the eye. /4

This goal is achieved in accordance with the invention through the characteristic features in Claim 1.

Through the invention an artificial lens is provided that is implanted in the lens capsular bag and whose optional portion can be exchanged. The suspension device (haptics + frame) for the optical part remains life long in the capsular bag and tissue grows around it, which leads to stable fixation and centralization. Since the suspension apparatus sits in the capsular bag at a metabolically inert location, life long toleration without tissue irritation is expected. Tolerance of the lens can be still increased by the haptics consisting of polymethylmethacrylate (PMMA). Preferably the entire lens consists of PMMA.

For exchangeable fastening of the optical part in the frame there are several possibilities. Hereby, a bayonet lock between the frame and optical part or also a screw lock between the frame and optical part or also the fitting of the optical part in a rotating inner groove of the frame with a reversible press fit of

the optical part in this inner groove are favorable.

To made the exchange easier through rotating the optical part with respect to the frame, the optical part and/or the frame have positioning holes that serve as gripping locations for a twisting tool. Preferably optical part (4) has holes placed peripherally at same angle intervals from one another and frame (2) has holes that are preferably diametrically opposed to one another.

From the literature listing mentioned above from "Gordon, R.A., Donzis, P.B.: Refractive development of the human eye. Arch. Ophthalmol. 103:785-789, 1985." a formula is known with which the given necessary refractive power of the lens to be implanted can be determined for each age level in children. According to these studies, in newborns an exchange of the optical part is necessary three times during childhood; in older children with accident-caused lens opacity at most one to two exchanges are necessary. The operative process for exchange of the optical part has been made possible through advances in the area of ophthalmological microsurgery. The opacity found inside the lens can be loosened, reduced in size and destroyed by means of ultrasound and then removed by vacuum. At the end of the operation the clear posterior lens capsule, the lens equator and a peripheral portion of the clear anterior lens capsule remains. These three components then form the capsular bag that is suspected by means of fine threads in the vitreous humor. In this so called capsular bag the intraocular lens with the

exchangeable optic is then implanted. The known advantages from the first two mentioned publications from Apple, et al. are then achieved with such capsular bag fixation. These are the following:

An anatomical, optically correct artificial lens position with good centering is achieved. There is only a small chance of lens slippage and decentralization. The lens implant can not tilt or tip. The maximum distance of the artificial lens from the cornea posterior surface lessens the danger of cornea opacities. The maximum distance of the artificial lens implant from the posterior surface of the iris, the ciliary process /5 and the vitreous humor prevents the danger of pigment leakage from chronic irritation with increase in internal eye pressure and bleeding. A liberation of inflammatory mediators from the vitreous humor is not possible, since the haptics are no longer in contact with it, with implantation in the capsular bag. In the vitreous humor no scars and blood vessel erosions are induced. Since the haptics are found in the capsular bag which is completely inert metabolically and contains neither blood vessels nor nerves, erosion of the artificial lens surface material is reduced. In addition, the probability of lens capsule opacity is extremely low, since the artificial lens offers a barrier effect against cataracts regrowing from the lens equator in small children. Further, there is the possibility of gently, operatively removing the artificial lens together with the lens capsule without destroying tissue, in case this is

should be necessary for clinical reasons.

In an advantageous manner the intraocular lens can have on the rear of the frame a circular strip that is preferably approximately 0.2 mm high. This strip forms a mechanical barrier against possible growth of lens material from the enveloping fold of the lens capsule. This construction reduces the number of operations that are necessary for opacity of the posterior lens capsule.

In the figures exemplary embodiments of the invention are shown. Using these figures the invention is more closely explained. They show:

Figure 1 a top view of a first exemplary embodiment with a bayonet lock;

Figure 2 a sectional representation of a bayonet lock;

Figure 3 a top view of a further exemplary embodiment;

Figure 4 a sectional representation of screw lock which can be used in the exemplary embodiment in **Figure 3**.

Figure 5 a sectional representation of a form closure lock which can be used in the exemplary embodiment in **Figure 3**.

In the exemplary embodiments shown an intraocular lens consists of perfectly circular ring-shaped frame **2** with even surfaces. In the ~~perfectly circ~~ular middle boring of frame **2** optical part **1** is found that is connected with a reversible lock, shown for the example forms in **Figure 2**, **4** and **5**, with frame **2**. On frame **2** haptics **3** are also fastened which have a hanger-shaped form in the exemplary embodiments. Other example forms could

also be used for the haptics, for example, a fastening bow, struts or the like.

On its back side, frame **2** has strip-shaped elevation **4** that is circular and runs around the same center as perfectly round optical part **1** and frame **2**. Optical part **1** has positioning hole **8**, whereby in the example forms shown four of this type of positioning hole are provided that are positioned 90° apart from one another. Positioning holes **9** can also be provided on frame 2. In the example forms shown, two positioning holes are involved that are diametrically opposed to one another.

The following dimensions can be chosen in the exemplary embodiments for the components of the intraocular lens: /6

The outer dimensions of the haptics are 8 to 9 mm apart; the diameter of the optical part is 4 to 5 mm. The outer diameter of the frame is 6 to 6.5 mm. The hangers used for haptics **3** have a diameter that is less than or equal to 0.16 mm. The positioning holes have a diameter of 0.2 mm. The strip-shaped elevation on the back of the frame has a height of approximately 0.2 mm.

The hanger-shaped haptics consist of PMMA. Frame **2** preferably likewise consists of an optically transparent material.

Optical part **1** is exchangeably placed in the middle opening of frame **2**. Hereby, it is possible to exchange optical parts with various refractive powers for one another, whereby frame **2** remains in the capsular bag.

In the example forms shown in **Figure 1** a reversible lock between frame **2** and optical part **1** of the lens is achieved with the help of bayonet lock **5**. This bayonet lock **5** is realized through a recess **10** provided on the inner circumference of frame **2** in which with insertion of optical part **1** in frame **2** a tab provided on the underside of optical part **1** is inserted. By rotating optical part **1** with respect to frame **2** tab **11** comes to rest under the frame part that neighbors recess **10** in the direction of rotation. Rotation can be carried out with help of a tool inserted into positioning holes **8**. Thereby, in positioning holes **9** of the frame, a tool can also be simultaneously inserted to create a corresponding opposing force during rotation.

Both surface parts of frame **2** and tab **11** which come to rest on one another after rotation can be built with a slant such that through wedging a securely fixed position of the optical part **1** is achieved in frame **2**. As an opposing position for this wedged bayonet lock, optical part **1** rests on the upper side of frame **2**, as shown in the sectional diagram in **Figure 2**. This rotating edge portion of optical part **1** also covers recess **10**.

With exchange of optical part **1**, this bayonet lock with frame **2** can be reversed by rotation in the opposite direction, whereby tab **11** comes to rest in recess **10** and the optical part can then be removed from the frame. The use of two bayonet locks **4** is preferred, as can be seen in **Figure 1**, that with respect to the middle of the lens, are found at diametrically opposed

positions with respect to one another.

A further reversible lock between optical part **1** and frame **2** can be screw lock **6** shown in **Figure 4**, that can be used in the example form in **Figure 3**. In this example form, frame **2** has on its inner circumference inner thread **12**, and optical part **1** has on its outer circumference outer thread **13**. By screwing these two threads **12** and **13** a reversible lock between frame **2** and optical part **1** is achieved.

In the example form shown in **Figure 5** the reversible fastening of optical part **1** in frame **2** uses a press fit. This press fit is realized by notch **15** on the inner circumference of frame **2** having corresponding tab **16** inserted that is formed on the outer circumference of optical part **1**. Preferably two press fits that are positioned diametrically opposed from one another are used, however, a grove circling the inner circumference of frame 2 can also be involved in which a corresponding shaped, circular tab on the outer circumference of optical part **1** is inserted.

Strip-shaped elevation **4** provided on the back of frame **2** forms a mechanical barrier against possible growth of lens material from the enveloping fold of the lens capsule. In contrast to known arrangements (US-PS Re 31 626 or US-PS 44 12 359) in the area of the optical part of the lens, elevation **4** is found on the underside of frame **2** in the example forms shown.

Patent Claims

1. Intraocular lens with an optical part and a frame that can be implanted in a capsular sack, in which the optical part can be inserted, is characterized by the optical part (1) rotatation with respect to the frame (2) being reversible such that even after successful first implantation, the optical part (1) being exchangeable in the frame that remains in the eye and by on the optical part (1) and.or on the frame (2) gripping locations (8, 9) being provided for a twisting tool.

2. Intraocular lens in accordance with Claim 1, is characterized by the optical part (1) being fastened by means of a bayonet lock (5) to the frame (2).

3. Intraocular lens in accordance with Claim 1, is characterized by the optical part (1) being fastened by means of a screw lock (6) to the frame (2).

4. Intraocular lens in accordance with Claim 1, is characterized by the optical part (1) being fastened in a circular inner groove of the frame (2) with a reversible press fit.

5. Intraocular lens in accordance with Claims 1 through 4, is characterized by in the optical part (1) and/or in the frame (2), positioning holes (8, 9) being provided as gripping locations.

6. Intraocular lens in accordance with Claim 1, is characterized by the optical part (1) peripherally having positioning holes (8) placed at the same angle intervals from one